REMARKS

Applicant has noted the rejections set forth in the office action mailed June 5, 2002. For the following reasons, Applicant respectfully traverses the rejections.

§ 112 Rejections

Claims 12 and 19 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the office action states: "The recitation of 'a diagnostic method comprising the step...' in claims 12 and 19 fails to point out what is being diagnosed." Applicant respectfully traverses this rejection since the claims particularly point out and distinctly claim a "diagnostic testing method", i.e. a general diagnostic tool.

As the MPEP points out, the indefiniteness requirement of §112, is "an objective [requirement] because it is not dependent on the views of the applicant or any particular individual, but is evaluated in the context of whether the claim is definite – i.e., whether the scope of the claim is clear to a *hypothetical person possessing the ordinary level of skill in the pertinent art*." MPEP §2171 (emphasis added). Furthermore, the MPEP points out: "*Breadth of the claim is not equated with indefiniteness.* If the scope of the subject matter embraced by the claims is clear, and if applicants have not otherwise indicated that they intend the invention to be of a scope different from that defined in the claims, then the claims comply with 35 U.S.C. 112, second paragraph." *In re Miller*, 441 F.2d 689, 169 USPQ 597 (CCPA 1971).

In the instant application, the preamble to claims 12 and 19 recite "a diagnostic testing method comprising the steps of..." In reading the preamble in the context of the entire claim, it is clear to one skilled in the art that the preamble refers to a general diagnostic tool. Moreover, the

application supports, and does not contradict, the reference to a "diagnostic testing method" in the preamble. Specifically, the application states that, "[t]he Ho-Hi-Ho epitopes of the present invention can be used in diagnostic tests, such as immunoassays, to detect viruses, microbes and malignant cells'' (see page 17, line 29; page 18, first line). Moreover, Applicant's reference to the use of PSA in the application is only an example and is not to be considered a limitation (see page 21, lines 12-13). Therefore, the scope of the claims is clear and the preamble is not indefinite. Accordingly, Applicant respectfully submits that the §112 rejection of claims 12 and 19 should be withdrawn.

§103(a) Rejection

Claims 12 and 19 are rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,554,101 issued to Hopp (hereinafter Hopp '101) and further in view of Hopp, Methods in Enzymology (1981) vol. 178, pp. 571-83 (hereinafter *Hopp* article). Specifically, the office action states that " [i]t would have been *prima facie* obvious to one of ordinary skill in the art to combine the teachings of U.S. 4,554,101 with the specific disclosed methods of hydrophobicity/hydrophilicity plotting in the Hopp's 1981 paper in order to identify and develop the specific epitope determinants of the instant invention."

Applicant respectfully traverses this rejection on the ground that claims 12 and 19 are not *prima facie* obvious over Hopp '101 in view of *Hopp* article. The MPEP provides that "the prior art reference (or references when combined) must teach or suggest *all the claim limitations*." MPEP §706.02(j)(emphasis added). Moreover, it is well established that a prior art reference must be considered in its entirety, including disclosures that "teach away" from the claimed invention. *See* MPEP §2141.02; §2145; *In re Grasselli*, 713 F.2d 731, 743, 218 USPQ 769, 779

(Fed. Cir. 1983).

First, Applicant respectfully submits that claims 12 and 19 both recite a step "wherein [the] epitope is characterized by a hydrophobic-hydrophilic-hydrophobic motif." However, neither Hopp '101 nor the *Hopp* article teach or suggest an epitope characterized by a hydrophobic-hydrophilic-hydrophobic (Ho-Hi-Ho) motif. On the contrary, both Hopp references refer to a method of selecting an epitope with the *highest local average hydrophilicity* (see Hopp '101, column 3, line 5; *Hopp* article, Fig. 1 Legend, page 572). This clearly is demonstrated by the list of identified epitopes that are presented in Hopp '101 (see Hopp '101, col. 10, 11 and 12). Therein, most of the epitopes contain only *hydrophilic amino acids* and do not contain even a single hydrophobic amino acid. For example, the H-epitope for the fiber protein of adenovirus type 2, Asn-Lys-Asn-Asp-Asp-Lys (see Hopp '101, col. 11, line 30)). Therefore, in both Hopp references, the emphasis is solely on hydrophilic regions and *not* on hydrophobic regions. As a result, the combination of Hopp '101 with the *Hopp* article fail to teach or suggest the limitation of a Ho-Hi-Ho epitope as recited in claims 12 and 19. Furthermore, because the Hopp references are seeking to select epitopes with the *highest local average hydrophilicity,* the references teach away from selecting a Ho-Hi-Ho epitope.

Second, Applicant respectfully submits that claims 12 and 19 further recite a method for obtaining a Ho-Hi-Ho epitope with an *optimal length of amino acids*. (See claim 12, (ii)(a)-(g); claim 19, (ii)(a)-(c)). However, neither Hopp '101 nor the *Hopp* article teach or suggest a method for obtaining the optimal epitope length as recited in claims 12 and 19. On the contrary, in reference to the size of the epitopes, the Hopp references only suggest a preferred selection of *six amino acids* for the production of a local hydrophilicity curve (see Hopp '101, col. 2, lines 50-55). The goal of the Hopp references was to set a "standard window length" in order to allow

two hydrophilicity plots to be compared. (See *Hopp* article, page 574). As recited in claims 12 and 19 of the instant application, specific steps must be taken to obtain an optimal epitope length for the instant invention and this optimal length will vary. The Hopp references fail to teach or suggest a *method for obtaining* such an optimal epitope length. Moreover, the *Hopp* article specifically states: "Different authors have chosen a variety of window lengths, and this has tended to impede a comparison of one method to another. Only by setting a standard window length can two plots be compared properly." (See *Hopp* article, page 574). Accordingly, the Hopp references teach away from obtaining an optimal epitope length other than a window length of 6 amino acids.

In view of the foregoing discussion, it is respectfully submitted that this case is in condition for allowance and such allowance is earnestly solicited.

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